

## EC DECLARATION OF CONFORMITY

MANUFACTURER:

TREK Diagnostic Systems 982 Keynote Circle, Suite 6 Cleveland, Ohio 44131

USA

**AUTHORIZED REPRESENTATIVE:** TREK Diagnostic Systems

Imberhorne Lane, East Grinstead

West Sussex, RH19 1QX

United Kingdom

## **DEVICES COVERED BY THIS DECLARATION:**

- 7101-44 VersaTREK® REDOX 1® 80 ml
- 7102-44 VersaTREK REDOX 1 80 ml with Stir Bar
- 7103-44 VersaTREK REDOX 2® 80 ml
- 7105-44 VersaTREK REDOX 1 EZ Draw<sup>®</sup> 40 ml
- 7106-44 VersaTREK REDOX 1 EZ Draw 40 ml with Stir Bar
- 7107-44 VersaTREK REDOX 2 EZ Draw 40 ml
- 7111-42 VersaTREK Myco
- 7112-42 VersaTREK Myco GS
- 7113-42 VersaTREK Myco PVNA
- 7114-42 VersaTREK Myco AS
- 7115-60 VersaTREK Myco Susceptibility Kit
- 7116-70 VersaTREK Myco PZA Kit
- 7150-44 VersaTREK Connector

## **DECLARATION STATEMENT:**

We hereby declare that the above-mentioned devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

## DATE OF VALIDITY:

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after 28 November 2003 and which bear the CE marking.

**AUTHORIZED SIGNATURE:** 

Teresa Anacker

Quality Assurance/Regulatory Affairs Manager

TREK Diagnostic Systems

Date: 14 March 2006